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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Laurence Hermitte

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9889

466

7590

07/31/2009

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EXAMINER

WESTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,442	Applicant(s) HERMITTE ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 - 33 is/are pending in the application.
- 4a) Of the above claim(s) 14, 18 - 20, 22, 24, 27, 30, 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 13, 15 - 17, 21, 23, 25, 26, 28, 29, 32, 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed May 26, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Applicants note on p 11 of their response that the previous Office Action did not expressly indicate that status of two other indefiniteness rejections. Applicant's attention is directed to the statement above, indicating that the following constitute the complete set of rejections and objections presently being applied.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 26, 2009 has been entered.

Claim Rejections - 35 USC § 112 – 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12, 13, 15 – 17, 21, 23, 25, 26, 28, 29, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Applicant has not fully complied with the written description provision for biocompatible polymers of natural origin wherein a said biocompatible polymer has grafted chains, each chain having a molecular weight less than 50,000 Da". The Examiner is unaware of any polymer of natural origin with grafted side chains and the specification does not provide written description for any such polymers. Applicant has also not met the written description provision for side chains of natural origin polymers of small size. No examples of such side chains are put forth. The examples utilize carboxymethyl cellulose as the side chain, but this polymer is not of natural origin as carboxymethyl groups are synthetically added to the natural origin cellulose.

4. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. None of the cellulose derivatives other than carboxymethyl cellulose meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus of derivatives of celluloses encompassed by the claim, since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base molecule, namely cellulose, may be changed while remaining a derivative.

5. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Applicant has not provided sufficient disclosure to meet the written description provision for “non-polymeric chains having antioxidant properties or properties for inhibiting reactions of

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degradation of said matrix". The examples given are vitamins, enzymes and cyclic molecules. These examples are diverse in structure and not part of an art recognized class. While these species within the genus meet the written description provision, they are insufficient to provide written description for the entire genus.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 12, 13, 15 – 17, 21, 23, 25, 26, 28, 29, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "complex matrix" in claims 12 and 33 is a relative term which renders the claim indefinite. The term "complex" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear if the structure recited in the body of the claim is sufficient to provide a "complex" matrix or if additional component(s) and/or structure(s) are required for the matrix to be deemed a "complex" one.

8. Claims 12, 13, 15 – 17, 21, 23, 25, 26, 28, 29, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the phrase "natural origin" in the phrase "biocompatible polymer of natural origin". It is unclear if this term is strictly limited to only those polymers which are isolated from natural sources or if the term also encompasses polymers containing monomers which are obtained from a natural such (i.e., the monomers are of natural origin) but the polymeric material itself is synthesized in a laboratory.

These claims are also indefinite because it is unclear to what the phrase "comprising polymers of natural origin of small size) in lines 7 – 8 of claims 12 and 33 is referring. This phrase could be referring to the biocompatible polymer of line 2 and is therefore partially redundant as a natural origin has already been required. Alternatively, it could be referring to the grafted chains wherein each chain has a molecular weight of less than 50,000 Da. The latter is also redundant as "small size" has been defined at ¶ [0038] of the PGPub of the instant application as having a size of less than 50,000 Da.

It is also unclear what type of molecular weight is being used if the grafted side chains are polymeric nature. For polymers, the molecular weight can be reported as a number average molecular weight, a weight-average molecular weight or viscosity-average molecular weight.

Claims 12 and 33 recite the limitation "number of moles of grafted molecules" in lines 12 – 13. There is insufficient antecedent basis for this limitation in the claim.

In calculating the quantity of grafting, it is also unclear which polymer is in the denominator when a polymer is grafted onto the biocompatible polymer of natural origin referenced in line 2.

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Please clarify.

9. Claims 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each claim recites the limitation "the grafted matrix". There is insufficient antecedent basis for this limitation in the claim.

10. Claim 33 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the phrase "non-polymeric chains having antioxidant properties or properties for inhibiting reactions of degradation of said matrix." The examples provided in specification include the natural origin polymers enzymes. But what properties inhibit matrix degradation reactions and therefore what materials are encompassed is not clear. Therefore, what non-polymeric chains fall within the scope of this limitation cannot be determined.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 12, 13, 17, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen (EP 0749982). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed November 24, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Nguyen described grafted polysaccharide compositions comprising a polysaccharide grafted with an antioxidant that can also be crosslinked. A minimal grafting level as low as 1 equivalent per 1000

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equivalents of polysaccharide to a maximum of 1 equivalent of antioxidant per 10 equivalents of polysaccharide. Nguyen fails to teach any composition that includes a biocompatible polymer having grafted chains, each chain comprising a molecules weight of less than 50,000 Da and comprising polymers of natural origin of small size, as featured in claim 12.

These arguments are unpersuasive. Claim 12 is indefinite as described above as one interpretation of the claim is a biocompatible polymer of natural origin with a small size. The antioxidant grafted polysaccharides of Nguyen meet the limitation of having grafted chains wherein each chain has a molecular weight of less than 50,000 Da (g/mol). The viscosity of the composition is a parameter that must be controlled when, for examples, injectable solutions such as those describe by Nguyen are prepared (p 7, ln 2 - 6). The viscosity of the composition is at least in part determined by the length and therefore molecular weight of the polymer chains. One of ordinary skill in the art would routinely optimize the length of the polymer chain to provide a composition with an appropriate viscosity that maintained the other desirable properties of the polymer. Claim 33 is the previous version of claim 12 that still includes the phrase "and/or non-polymer chains having antioxidant properties", which is the basis of Nguyen's invention.

New claims 32 and 33 recite that "the force ejection of the grafted matrix having grafted chains is decreased in respect to a non-grafted matrix". The same compositions must have the same physical properties. The cited prior art described a polysaccharide of natural origin (hyaluronic acid) with grafted side chains where each chain has a molecular weight of less than 50,000 Da. The instant claims recite a polysaccharide of

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natural origin with grafted side chains where each chain has a molecular weight of less than 50,000 Da. The amount of grafting in the compositions overlaps between the cited prior art and the instant claims. Therefore, the compositions of the cited prior art must have a force ejection of the grafted matrix having grafted chains that is decreased in respect to a non-grafted matrix as both the cited prior art and the instant claims recite a polysaccharide of natural origin with grafted side chains where each chain has a molecular weight of less than 50,000 Da.

15. Claims 12, 13, 16, 23, 29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen further in view of Ramamurthi (J Biomed Mater Res 2002). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed November 24, 2008 and those set forth herein.

Applicant traverses this rejection on the grounds that Ramamurthi also fails to teach compositions that have a biocompatible polysaccharide of natural origin with grafted side chains where each chain has a molecular weight of less than 50,000 Da and comprising polymers of natural origin of small size.

This argument is unpersuasive. As discussed above, the claims are indefinite and are not limited to the interpretation set forth by Applicant. Nguyen teaches polymers that fall within the scope of the invention so the rejection is maintained.

16. Claims 12, 13, 15, 21, 32 and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen further in view of Bolotin (US 2003/0224974). This rejection

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is MAINTAINED for the reasons of record set forth in the Office Action mailed November 24, 2008 and those set forth herein.

Applicant traverses this rejection on the grounds that Bolotin also fails to teach compositions that have a biocompatible polysaccharide of natural origin with grafted side chains where each chain has a molecular weight of less than 50,000 Da and comprising polymers of natural origin of small size.

This argument is unpersuasive. As discussed above, the claims are indefinite and are not limited to the interpretation set forth by Applicant. Nguyen teaches polymers that fall within the scope of the invention so the rejection is maintained.

17. Claims 12, 13, 16, 23, 29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen further in view of Bolotin and Ramamurthi. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed November 24, 2008 and those set forth herein.

Applicant traverses this rejection on the grounds that Bolotin and/or Ramamurthi also fails to teach compositions that have a biocompatible polysaccharide of natural origin with grafted side chains where each chain has a molecular weight of less than 50,000 Da and comprising polymers of natural origin of small size.

This argument is unpersuasive. As discussed above, the claims are indefinite and are not limited to the interpretation set forth by Applicant. Nguyen teaches polymers that fall within the scope of the invention so the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW